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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,728	08/23/2002	Gian Luigi Gessa	2503-1008	1193

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 05/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,728	GESSA ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments and Remarks received 2/8/05 is acknowledged. Claims 5-12 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-12 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 4,156,013 to Bruinvels et al.

Bruinvels et al disclose a method for treating patient from suffering from anxiety neurosis, anxiety like neurosis, and alcoholism. See title. The patient is treated by administering baclofen in the amount of 15-60 mg per day. See column 1, lines 44-56 and claim 1. The dose of baclofen is given in a tablet or suppository form. See claim 3. Bruinvels discloses the administration of the drug freed patients from craving for alcohol. See column 2, lines 31-32.

It should be noted that reducing the craving of alcohol reads on "promoting abstinence".

Response to Arguments

Applicant argues that Bruinvels does not constitute an enabling disclosure. Applicant argues that the prior art teaches the treatment of anxiety and neurosis but this does not enable one to treat alcoholism. Applicant further argues that anxiety disorders and alcoholism are two different mental disorder and anxiety is not part of alcoholism.

Applicant's arguments filed 2/8/05 have been fully considered but they are not persuasive. Firstly, it should be noted that the instant rejections are made under anticipation; thus applicant's arguments such as "reasonable expectation of success" do not pertain to a rejection made under anticipation. Further, Bruinvels *expressly* discloses the treatment of alcoholism on column 2, lines 31-32 wherein the prior art discloses that when baclofen was administered to patients, not only was anxiety treated but the craving for alcohol was also treated, i.e. alcoholism.

With regard to applicant's argument that treating alcoholism was an "incidental observation", the prior art accidentally or intentionally observed the efficacy of baclofen in treating alcohol craving is irrelevant; it still constitutes prior art. Further, it is pointed out that "the use of patent as references is not limited to what the patentees describe as their own inventions or to the problems which they are concerned. They are part of the literature of the art, relevant for all they contain." See *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (1983). Thus, regardless of Bruinvel's primary goal, i.e. treating anxiety, Bruinvels clearly discovered that baclofen also treats alcoholism.

With regard to applicant's assertion that Bruinvels is non-enabling, the examiner points out that when the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). In instant case, the mere "historical evidence" that Bruinvels did not pursue the invention further, does not make the patent non-enabling. Applicant's beliefs without evidence is not enough to remove prior art as non-enabling.

Moreover, it is noted that Bruinvels supposedly non-enabling disclosure teaches the *instant* dosage amount.

Lastly with regard to applicant's argument that anxiety is not related to alcoholism, although this irrelevant, the examiner will address the argument nonetheless. The examiner points to Saitz (Introduction to Alcohol Withdrawal, Alcohol Health Res. World, 1998; 22(1):5-12) as art of interest wherein the reference discloses that signs and symptoms of alcohol withdrawal includes tremors, irritability, **anxiety**, or **agitation**. It should be noted that the reduction of one symptom or condition of said disease, constitutes *treatment* of the disease.

Claims 5-7 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 4,126,684 to Robson et al.

Robson et al disclose the treatment of withdrawal symptoms observed after the interruption of prolonged use of addicting agents and the reduction of addiction liability with 4-amino-3p-halophenylbutyric acids and their derivatives. See abstract. Among the addicting agents taught is alcohol. See column 2, line 37. The general dose is 0.01-5 mg/kg/day or a single dosage unit of 1-10 mg per day of baclofen. See column 2, lines 60-63 and claim 7. The inventive method of reducing the addiction liability comprises the oral, anal, parenteral administration baclofen. See column 3, lines 42-46.

It should be noted that reducing addiction reads on "promoting abstinence".

Response to Arguments

Applicant argues that Robson discloses treating withdrawal symptoms of morphine with baclofen but this teaching does not extend to alcohol. Applicant argues that opioids and alcohol possess different mechanisms of action and have different neurobiological bases and therapeutic

approaches. Applicant argues that Robson does not enable a skilled artisan to practice the instant invention since any theoretical generalizations from opioid dependence to alcohol dependence is not supported by evidence.

Applicant's arguments filed 2/8/05 have been fully considered but they are not persuasive. As discussed above, the burden is on applicant to provide facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). While the examiner notes the prior art submitted by applicant, it is the examiner's position that these references do not render Robson non-enabling. The prior art submitted by applicant demonstrates that specific drugs that treat opioid addiction do not treat alcoholism. Firstly, it should be noted that these drugs are unrelated to the presently claimed drug. Secondly, it is noted that the applicant is merely demonstrating that certain drugs that treat opioid addiction do not necessarily treat alcoholism. Summarily, applicant is demonstrating the unpredictability of treating alcoholism with drugs that treat opioid addiction. This type of evidence may pertain to a rejection made under obviousness wherein the primary reference does not expressly teach the addictive agent as alcohol, but not in a rejection wherein alcohol is expressly taught. Moreover teaches the same dosage amount as applicant and thus the instant methodology as claimed, is not distinguishing over the prior art.

Claims 5-6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by over XP-001036625 (File et al, Effects of Baclofen and Nitrendipine on Ethanol Withdrawal Responses in the Rat, Neuropharmacology, 1991 February 30 (2), 183-90).

File et al disclose administering 1.25 mg/kg or 2.5-mg/kg baclofen vehicle to analyze the effects of baclofen on ethanol withdrawal responses in rats. See page 186 and abstract. File et al

disclose that the chronic exposure to animals and humans to ethanol results in development of physical dependence . See page 183. File discloses baclofen reduces the enhanced aggression during withdrawal of ethanol and reduced the withdrawal tremor. See abstract and Discussion section.

It is the examiner's position that the recitation "a method of promoting abstinence" occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites **the purpose of a process** or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In instant case, the prior art's and instant method steps are the same; thus meeting the preamble limitation.

Response to Arguments

Applicant argues that the effect of baclofen on some alcohol-induced responses does not enable one to practice the claimed invention. Applicant argues that File is not enabling. Applicant argues that at the time the invention was made, the prior art at the time had many discrepancies.

Applicant's arguments filed 2/8/05 have been fully considered but they are not persuasive. As discussed above, the examiner points out that the mere discrepancies of the prior art do not make a reference itself non-enabling. The threshold for rendering a reference non-enabling is high and it is the applicant's burden to *prove* that a reference is not enabling. The examiner points out that this may be done by proving that the dosage amount, route of

administration, etc. of the prior art does not treat alcoholism. Applicant has not done so. In fact applicant has not claimed any dosage amount, or administration steps that distinguish the instant method from the prior art.

Additionally, the examiner points out that the treatment of withdrawal symptoms in a subject that is abstaining from alcohol does fall within the scope of treating alcoholism. Alcoholism is defined as "1 : continued excessive or compulsive use of alcoholic drinks 2 a : poisoning by alcohol b : a chronic disorder marked by excessive and usually compulsive drinking of alcohol leading to psychological and physical dependence or addiction." Therefore, the treatment of one of the symptoms, i.e. the withdrawal syndrome, does treat the condition since withdrawal can cause relapse, i.e. drinking excessively again. See art on interest Becker, Kindling in alcohol withdrawal, Alcohol Health Res World, 1998; 22(1): 25-33. It should be noted that the reduction of one symptom or condition constitutes *treatment* of the disease.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-9 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over XP-001036625 (File et al, Effects of Baclofen and Nitrendipine on Ethanol Withdrawal Responses in the Rat, Neuropharmacology, 1991 February 30 (2), 183-90).

File et al teach administering 1.25 mg/kg or 2.5-mg/kg baclofen vehicle to analyze the effects of baclofen. See page 186 and abstract. File et al teach that the chronic exposure to animals and humans to ethanol results in development of physical dependence . See page 183. File teaches baclofen reduces the enhanced aggression during withdrawal of ethanol and reduced the withdrawal tremor. See abstract and Discussion section.

File et al do not teach the daily dosage amount or administration to humans..

Although File utilizes an animal model, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by File et al and utilize baclofen to treat humans for alcohol withdrawal. One would have been motivated to do so since it is conventional in the pharmaceutical industry and its research to draw conclusions from animal models and apply them to humans. Further, it can be ascertained from File et al's disclosure wherein File links humans and animals that the animal model is intended to apply to human treatment. Therefore, it is prima facie obvious to look to the disclosure of File and apply it to human treatment of alcoholism with a reasonable expectation of success.

Further, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of File et al and ascertain the appropriate dosage amount. One would have been motivated to do so since File teaches an amount of 1.25 mg/kg or 2.5-mg/kg

baclofen wherein the dosage amount is based on the weight of the subject treated. Therefore, the daily dosage amount would be dependent on the patient and his/her weight.

Conclusion

None of the claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
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